

REMARKS

Claims 68-70, 72, 73, and 75-88 were pending. Claims 68-70, 72, 73, and 88 have been amended. Claims 86 and 87 have been cancelled. Therefore, claims 68-70, 72, 73, 75-85, and 88 are currently pending.

No new matter has been added. Claims 68-70, 72, 73, and 88 have been amended to clarify the invention. Support for the amendments to claims 68-70 can be found in the claims as originally filed.

Rejection of Claims 68-70, 72-73, and 75-85 under 35 U.S.C. § 102(b)

Claims 68-70, 72-73, and 75-85 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kaddurah-Daouk *et al.* (WO 96/14063).

Claim 68 and its dependent claims are directed to method for increasing energy reserves in the skin of a subject who is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. The method includes administering to the subject an effective amount of creatine or a salt thereof. Claim 69 is directed to a method for sustaining energy production in the skin of a subject who is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. The method includes administering to the subject an effective amount of creatine. Claim 70 is directed to a method for modulating energy flow in the skin of a subject who is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. The method includes administering to a subject an effective amount of creatine or a salt thereof, such that the energy flow in the skin of said subject is modulated.

According to the Examiner, Kaddurah-Daouk *et al.* describes "treatment of diseases of the nervous system comprising administering creatine or its salts to the subject wherein creatine compounds (creatine or its salts) are used for modifying energy of cells in stress via increasing energy reserve, sustaining energy production, and modulating energy flow."

Applicants submit that Kaddurah-Daouk *et al.* is directed to treatment of diseases of the nervous system. Kaddurah-Daouk *et al.* neither teaches nor suggests administering creatine or its salts to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. Therefore, Applicants respectfully request that this rejection of claim 68-70, 75-80, and 84-85 be withdrawn.

Rejection of Claims 68-70, 75-76, and 84-86 under 35 U.S.C. § 102(b)

Claims 68-70, 72-73, and 75-86 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kaddurah-Daouk *et al.* (US 5,321,030). Claim 86 has been cancelled, thus rendering its rejection moot.

As described above, Applicant's claims are directed to methods for increasing energy reserves in the skin of a subject, sustaining energy production in the skin of a subject, and modulating energy flow in the skin of a subject who is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. The methods include administering to a subject an effective amount of creatine or a salt thereof.

According to the Examiner, Kaddurah-Daouk *et al.* describes "a creatine (or its salts) and it[s] use as an antiviral agent for treating various diseases associated with variety of viruses via modifying energy levels on the cells."

Applicants submit that Kaddurah-Daouk *et al.* is directed to use of creatine as an anti-viral agent. Kaddurah-Daouk *et al.* neither teaches nor suggests administering creatine or its salts to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. Therefore, Applicants respectfully request that this rejection of claim 68-70, 72-73, and 75-85 be withdrawn.

Rejection of Claims 68-70 and 75-88 under 35 U.S.C. § 103(a)

Claims 68-70 and 75-88 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Greff (FR 2725896) and/or Courtin (FR 2734721), in view of Kaddurah-Daouk *et al.* (US 5,321,030 or WO 96/14063). Claims 86 and 87 have been cancelled, thus rendering their rejection moot.

As described above, Applicant's claims are directed to methods for increasing energy reserves in the skin of a subject, sustaining energy production in the skin of a subject, and modulating energy flow in the skin of a subject who is suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. The methods include administering to a subject an effective amount of creatine or a salt thereof.

Greff describes the use of fermentation products containing amino acids in cosmetic compositions for stimulating phosphocreatine synthesis, stimulation of cellular growth, and reducing skin wrinkles. Greff fails to teach or suggest methods using an effective amount of creatine or its salts as claimed by Applicant.

Courtin is directed to "sunlight-activated cosmetic compounds for protection against the skin aging using ... a precursor of vitamin D which is transformed into vitamin D under the action of the sunlight." Courtin's composition also contains "vitacreatine" which is defined in CAS to be "a complex mixture obtained through the fermentation of selected lactobacilli; used in a cosmetic preparation."

Both Greff and Courtin fail to teach or suggest Applicant's claimed methods which include administering an effective amount of *creatine or a salt thereof* such that energy reserves in the skin of a subject are increased, energy production in the skin of a subject is sustained, or energy flow in the skin of a subject is modulated. In contrast, Courtin and Greff teach using a complex mixture of various components contained in fermentation broth. Neither Greff nor Courtin, alone or in combination, teach or suggest administering creatine or a salt thereof to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue as claimed by Applicant.

Both US 5,321,030 and WO 96/14063 fail to overcome the deficiency of Greff and Courtin. Neither U.S. 5,321,030 nor WO 96/14063 teach or suggest the administration of creatine or a salt thereof to a subject suffering from a skin disorder associated with free-radicals, aging, sun radiation, stress or fatigue. It would have not been obvious to an ordinarily skilled artisan to combine the teachings of Greff and/or Courtin with either US 5,321,030 and/or WO 96/14063, because both Greff and Courtin are directed to the use of complex fermentation mixtures, rather creatine or its salts as claimed by Applicant.

Therefore, Applicant requests that this rejection of claims 68-70, 72, 73, 75-85, and 88 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 68-70, 72, 73, and 75- 88 under Judicially Created Doctrine of Obviousness-Type Double Patenting

Claims 68-70, 72, 73, and 75-88 were rejected under the judicially created doctrine of obviousness type double patenting over claims of U.S. Patent No. 6,242,491. The Office Action indicates that a timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.312 (c) may be used to overcome a rejection based on a non-statutory double patenting ground provided the patent is shown to be commonly owned with this application. It is respectfully submitted that a terminal disclaimer will be filed upon an indication of allowable subject matter, if appropriate.

SUMMARY

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of the claims and/or amendments to the claims are being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application. The amendments made to the claims are not related to any issues of patentability.

In view of the above remarks and amendments, it is believed that this application is in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call Elizabeth A. Hanley, Esq. at (617) 227-7400.

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